

MEMORANDUM

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To: Green Ribbon Science Panel, Subcommittee 3

Re: Quality Assurance for Alternatives Assessments

Date: June 13, 2011

This is in response to the request for written statements made during the May 31, 2011 public meeting by telephone conference of Subcommittee 3 of the Green Ribbon Science Panel.

These remarks address one issue: how to reconcile industry's desire to claim trade secret/CBI status for information used in AA's and still ensure that the public and other interested third parties, such as industrial users of chemicals, will reasonably have confidence in the results of those AA's.

I would like to propose two quality assurance tracks – a "CBI AA Quality Assurance Program" for AA's that rely on trade secret/CBI information and a "Transparent AA Quality Assurance Program" for AA's that do not.

CBI AA Quality Assurance Program.

It seems clear that under regulations that DTSC will be proposing, industry will be entitled to claim trade secret or CBI status for substantial information that will be material to AA's. This could conceivably even extend to the AA algorithms that companies develop for performing AA's. Given the purpose of trade secret/CBI claims, such information will never be divulged to the public, either during or at the end of the AA process or even in the context of eventual regulatory responses. We have to assume that these AA's will never be transparent, and that their quality and the judgments they employ will never be meaningfully assessed by the public or by other interested third parties.

For CBI-containing AA's, I believe that a substantial program of third party review will be essential both (a) to ensure substantive quality of the AA's and (b) to provide the public and others with a reasonable basis for relying on the AA results. To have any hope of achieving those goals, this CBI Quality Assurance Track will have to include an accreditation and certification program for AA assessors; a substantive review by independent third-party assessors; private sector financial support for the assessment program; robust mechanisms for preventing conflicts of interests; a process whereby DTSC can resolve disputes among different assessors as to how AA's should be conducted; and DTSC oversight and programmatic quality assurance

to the public.

Transparent AA Quality Assurance Program.

Industry claims of trade secret and CBI status are voluntary, and are made at the discretion of the party that owns the information. Accordingly, it should be possible in principle to perform AA's based entirely on information for which no trade secret and CBI claims are made. In such cases, AA's could be made fully transparent. If AA's were made fully available to the public and to other interested third parties, they would be in a position to perform substantive reviews of the quality of the AA's and of the judgments they employ.

For transparent AA's, DTSC could implement a very simple quality assurance program. This program could forgo the formal independent third party review and rely for quality assurance instead on members of the public and civil society, including the NGO community, academics, competitors, manufacturers of potential alternatives and other interested third parties. Such a program would still require an accreditation and certification program for assessors, some opportunity for meaningful public input, including a petition process for DTSC review where problems with an AA are found, and DTSC oversight and programmatic quality assurance. But it would be much simpler and substantially less expensive for private parties than would any effective CBI-AA Quality Assurance Program.

The essential trade off between these two quality assurance programs is that the public and other interested parties would have to provide quality assurance in cases where industry makes AA's transparent, while industry would have to bear the cost of a more elaborate quality assurance program in cases where it chooses to make trade secret/CBI claims.